Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
RDC60M/PCT		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/004406	29.03.2004	11.07.2003

International Patent Classification (IPC) or national classification and IPC

A61L27/00

Applicant

JAPAN SCIENCE AND TECHNOLOGY AGENCY

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/004406

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/004406

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-8	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-8	NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents are cited in the international search report:

Document 1: JP 2002-325834 A (Japan Science and Technology Corp.)

Document 2: JP 2002-248163 A (Japan Science and Technology Corp.)

Document 3: JP 2002-272835 A (Naoshi Ozawa)

Document 1 discloses a titanium oxide-organic polymer composite material for use as synthetic bone, which is obtained by subjecting a substrate comprising a polymer compound to a titania solution treatment wherein said substrate is immersed for 24 hours in a room-temperature solution obtained by adding a solution comprising acidic ethanol and water to an ethanol solution of titanium oxide tetraisopropyl, thereby forming a titania gel on the surface of the aforementioned substrate, and then subjecting the substrate on which the titania gel is formed to an immersion treatment in a 40°C solution to which water or acid warmed to 80°C is added, thereby denaturing the gel to a titanium oxide film which can form apatite having a Ca/P atom ratio which is the same as that of mammalian

animal bone from a supersaturated apatite aqueous solution or body fluids of a mammalian animal.

Moreover, document 1 states that any organic polymer can be used as long as it is compatible with mammals such as humans and can form a titania layer that can form apatite in a supersaturated apatite aqueous solution, and indicates that an organic polymer which includes a hydroxyl group and/or a derivative thereof, …and an amino group is a suitable material for such use.

The inventions set forth in claims 1 to 8 of the present international application differ from the invention disclosed in document 1 in that the former do not use a silane coupling agent that forms a Si-OH group on the substrate surface, and as disclosed in document 1 (paragraph [0013]), when a polyolefin that does not have a functional group is used on the surface, the use of a silane coupling agent is required in the latter. However, each of documents 2 and 3 discloses polyethylene terephthalate and nylon as organic materials other than polyolefins which can directly form a titanium oxide layer on the surface through aqueous solution synthesis, and these substances have on their terminal a group such as a hydroxyl, amino, or carboxyl group. Further, when seen in bulk form as a substrate, regardless of whether the aforementioned functional groups are present on the terminal or on a side chain of the organic polymer, it is obvious to a person skilled in the art that said functional groups are present on the substrate surface.

Thus, adapting the invention disclosed in document 1 by using a polyester or nylon as the polymer compound, and when doing so, trying to form a titanium layer

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

without the use of a silane coupling agent, would be obvious to a person skilled in the art.

Further, the effect of doing so is not recognized as an exceptional feature unpredictable by a person skilled in the art.